K031588/A2

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Division of Immunology and Hematology, Office of In Vitro Device Evaluation and Safety
Center for Devices and Radiological Health, Food and Drug Administration
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

RE: CellSearch™ Epithelial Cell Kit/Cell Spotter™ Analyzer #K031588: Request for Evaluation of Automatic Class III Designation under 513(f)(2)

Dear FDA:

Veridex, LLC (Veridex) is providing the following petition in response to receipt of a not substantially equivalent (NSE) determination. We believe the documentation in CellSearch™ Epithelial Cell Kit/CellSpotter™ Analyzer #K031588 is sufficient to substantiate the Class II pursuant of 513(f).

510(k) Number for NSE finding:
Veridex respectfully requests that premarket notification #K031588 be considered for a risk-based classification of the CellSearch™ Epithelial Cell Kit/CellSpotter™ Analyzer. A "not substantially equivalent" decision was rendered for #K031588 on December 24, 2003.

Statement of Cross Reference to 510(k):
Veridex hereby cross-references information contained in 510(k) #K031588.

Classification Being Recommended:
Veridex believes the documentation presented in premarket notification #K031588 is sufficient to substantiate an order classifying CellSearch™ Epithelial Cell Kit/CellSpotter™ Analyzer as Class II (general and special controls) pursuant to section 513 of the Federal Food, Drug, and Cosmetic Act.

Potential Benefits:
The benefits derived from using this device outweigh the possible risks associated with use of the product as an aid to diagnosis. For the CellSearch™ Epithelial Cell Kit/CellSpotter™ Analyzer #K031588 , the advantages and risks are the following.

Currently, for patients with metastatic breast cancer, the choice of therapy regimen is dictated by factors such as hormone receptor status and extent of disease. The clinical advantage of enumeration of circulating tumor cells (CTCs) is to provide a tool to evaluate the efficacy of therapy in patients under treatment for metastatic breast cancer. The presence of CTCs above a

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pre-defined cut-off of greater than or equal to 5, or that rise above the cut-off, predicts a poor outcome. In patients with metastatic breast cancer the presence of CTCs above the cut-off predicts a lower probability of responding to therapy, shorter time to progression and shorter overall survival. Conversely, a CTC count below the threshold and a CTC count that decreases to below the threshold predict a higher probability of response to therapy, longer progression free survival, and longer overall survival. As demonstrated in the multivariate Cox Regression analysis, CTC count was the strongest predictor of Progression Free Survival and Overall Survival. The predictive utility of CTCs in patients with metastatic breast cancer represents a useful adjunct to existing methods including biological markers, physical examination and imaging.

The risk of CTC enumeration results from false negative and false positive results. A false negative test result has minimal impact, as the patient would likely continue on their therapy. A false positive result could lead to a decision to terminate an effective therapy. Because of the potential for false positive results, CTC results should be interpreted in conjunction with accepted methods for monitoring and managing patients with metastatic cancer such as; imaging, other laboratory based tests, and physical examination including the individual patient perspective on the effectiveness of their therapy.

Proposed General and Special Controls:

Veridex believes that general controls and special controls in accordance with FDA's draft Class II Special Control Guidance Document: "Immunomagnetic Circulating Tumor Cell (CTC or Circulating Cancer Cell (CCC)) Selection and Enumeration Systems" constitute adequate information to ensure reasonable assurance of the safety and effectiveness of CellSearch™ Epithelial Cell Kit/CellSpotter™ Analyzer #K301588 via the premarket notification process 21 CFR 807. These controls parallel the safety and effectiveness information provided in #K031588 for its intended use as:

The CellSearch™ Epithelial Cell Kit is intended for the enumeration of circulating tumor cells (CTC) of epithelial origin (CD45-, EpCAM+, and cytokeratins 8, 18+ and/or 19+) in whole blood in conjunction with the CellPrep™ Semi-Automated Cell Preparation System, the CellSpotter™ Analyzer and the CellSearch™ Control Cell Kit. The CellSpotter™ Analyzer is a semi-automated fluorescence microscope intended to enumerate fluorescently labeled cells that are immuno-magnetically selected and distributed over a viewing surface.

The presence of CTC in the peripheral blood, as detected by the CellSearch™ Epithelial Cell Kit, is associated with decreased progression free survival and decreased overall survival in patients treated for metastatic breast cancer. A CTC count of 5 or more per 7.5 mL of blood is predictive of shorter progression free survival and shorter overall survival.

If you have questions or need additional information, please contact me at the address above or by telephone at (908) 704-3942.

Regards,

Debra J Rasmussen

Debra J. Rasmussen
Director of Regulatory Affairs